PMUSA Clinical Evaluation
Study Initiation Visit

Required Attendees: (**BOLD** = *core study team members)*

- ☐ **PMUSA Study Manager**
- ☐ **CRO Project Manager**
- ☐ **CRO Study Manager**
- ☐ **CRO Principal Investigator**
- ☐ Key site clinical team members
  - o Pharmacist
  - o Topography downloader(s)) (at least 2)
  - o WatchPC downloader(s) (at least 2)
  - o
- ☐ Site Lab Director
- ☐ **Monitoring CRO Project Manager**
- ☐ Plowshare Technologies trainer (as needed)
- ☐ Interfusion Partners, Inc. trainer (as needed)
- ☐ ETS evaluator (as needed)
- ☐
- ☐

Agenda

1) **Review Protocol, Attachments, Procedures, ICF, CRF, Study Plan, and Applicable PMUSA Clinical Processes.**
Verify adequate knowledge by all parties. Identify and resolve gaps and issues.

   a) informed consent process

   b) subject check-in procedures (both confinement and ambulatory visits)

   c) subject randomization procedure

   d) study product accountability (shipping and receiving logs, dispensation, returns, disposal) and storage

   e) study supplies ordering/replenishment procedures

   f) subject enrollment, activity, and termination logs

   g) AE, SAE definitions and reporting requirements (including emergency contact info)

   h) sample collection (e.g., blood, 24-h urine, sputum)

   i) early termination procedures including flagging incomplete 24-h collections

(e.g., urine, cig consumption)

j) clear lines of communication and timelines established to communicate:
   - protocol changes (i.e., amendments, administrative changes)
   - protocol exceptions, deviations, violations
   - key personnel changes
   - site or monitoring problems/issues

   i) core study team teleconference schedule throughout study conduct and monitoring periods

   ii) weekly teleconference between PMUSA Clinical Study Team and CRO Project and Study Managers

   iii) timeframe for visit monitoring reports to PMUSA Study Manager (with respect to completion of monitoring visit):
   (1) **verbal** within 24 h
   (2) **electronic** copy via e-mail within 12 workdays
   (3) signed copy of final **written** report via ground USPS within 20 workdays

k) roles, responsibilities, and experience of all study personnel

l) protocol compliance and procedural performance standards requirements

m) monitoring plan (scope and schedule of visits)

   i) clinical conduct procedures and data

   ii) data and regulatory requirements

n) study records retention requirements

2) Tour site. ***Required for* Site *Initiation Visits.* *As needed for* Study *Initiation Visits.***
Verify adequate training and procedure performance (per GCP and protocol) including troubleshooting. Identify and resolve gaps and issues.

a) sleeping/living/dining quarters including verification of adequate measures to prevent cross-contamination of ventilation of the different study groups' quarters

b) study product storage areas and storage condition-monitoring logs

c) study-specific procedures

d) on-site lab and sample collection and processing areas (particularly timed urine collections)

e) sample storage areas, equipment (e.g., freezers), and storage condition-monitoring logs

3) Review training records of key site personnel

4) Review applicable key site SOPs

LEGEND

AE	*adverse event*
CE	*Clinical Evaluation*
CRA	*Clinical Research Associate*
CRF	*case report form*
CRO	*Clinical Research Organization*
CSR	*clinical study report*
ETS	*environmental tobacco smoke*
GCP	*Good Clinical Practices*
ICF	*informed consent form*
PMUSA	*Philip Morris USA, Inc.*
QC	*quality control*
SAE	*serious adverse event*
SAP	*statistical analysis plan*
SOP	*standard operating procedure*